



## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 180

[EPA-HQ-OPP-2021-0356; FRL-9839-01-OCSP]

### Spiropidion; Pesticide Tolerances

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Final rule.

**SUMMARY:** This regulation establishes tolerances for residues of the insecticide spiropidion and its metabolites and degradates in or on multiple commodities which are identified and discussed later in this document. Syngenta Crop Protection, LLC requested these tolerances under the Federal Food, Drug, and Cosmetic Act (FFDCA).

**DATES:** This regulation is effective [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Objections and requests for hearings must be received on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*] and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPP-2021-0356, is available at <https://www.regulations.gov> or at the Office of Pesticide Programs Regulatory Public Docket (OPP Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room and the OPP Docket is (202) 566-1744. Please review the visitor instructions and additional information about the EPA Docket Center and Reading Room that are available at <https://www.epa.gov/dockets>.

**FOR FURTHER INFORMATION CONTACT:** Marietta Echeverria, Acting Director, Registration Division (7505T), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Avenue, NW., Washington, DC 20460; main telephone number: (202) 566-1030; email address: *RDFRNotices@epa.gov*.

**SUPPLEMENTARY INFORMATION:**

**I. General Information**

*A. Does this Action Apply to Me?*

You may be potentially affected by this action if you are an agricultural producer, food manufacturer, or pesticide manufacturer. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Crop production (NAICS code 111).
- Animal production (NAICS code 112).
- Food manufacturing (NAICS code 311).
- Pesticide manufacturing (NAICS code 32532).

*B. How Can I Get Electronic Access to Other Related Information?*

You may access a frequently updated electronic version of EPA's tolerance regulations at 40 CFR part 180 through the Office of the Federal Register's e-CFR site at <https://www.ecfr.gov/current/title-40>.

*C. How Can I File an Objection or Hearing Request?*

Under FFDCFA section 408(g), 21 U.S.C. 346a, any person may file an objection to any aspect of this regulation and may also request a hearing on those objections. You must file your objection or request a hearing on this regulation in accordance with the instructions provided in 40 CFR part 178. To ensure proper receipt by EPA, you must identify docket ID number EPA-HQ-OPP-2021-0356 in the subject line on the first page

of your submission. All objections and requests for a hearing must be in writing and must be received by the Hearing Clerk on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Addresses for mail and hand delivery of objections and hearing requests are provided in 40 CFR 178.25(b).

In addition to filing an objection or hearing request with the Hearing Clerk as described in 40 CFR part 178, please submit a copy of the filing (excluding any Confidential Business Information (CBI)) for inclusion in the public docket. Information not marked confidential pursuant to 40 CFR part 2 may be disclosed publicly by EPA without prior notice. Submit the non-CBI copy of your objection or hearing request, identified by docket ID number EPA-HQ-OPP-2021-0356, by one of the following methods:

- *Federal eRulemaking Portal*: <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be CBI or other information whose disclosure is restricted by statute.

- *Mail*: OPP Docket, Environmental Protection Agency Docket Center (EPA/DC), (28221T), 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001.

- *Hand Delivery*: To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at

<https://www.epa.gov/dockets/contacts.html>.

Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <https://www.epa.gov/dockets>.

## **II. Summary of Petitioned-For Tolerance**

In the *Federal Register* of June 28, 2021 (86 FR 33924) (FRL-10025-08), EPA issued a document pursuant to FFDCFA section 408(d)(3), 21 U.S.C. 346a(d)(3), announcing the filing of a pesticide petition (PP 0E8880) by Syngenta Crop Protection, LLC, P.O. Box 18300, Greensboro, NC 27419-8300. The petition requested that 40 CFR

part 180 be amended by establishing tolerances for residues of the insecticide spiropidion, [3-(4-chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-2-oxo-1,8-diazaspiro[4.5]dec-3-en-4-yl ethyl carbonate] and its metabolite SYN547305 [3-(4-chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-1,8-diazaspiro[4.5]decane-2,4-dione; and 2-(4-chloro-2,6-dimethyl-phenyl)-1-hydroxy-8-methoxy-4-methyl-4,8-diazaspiro[4.5]dec-1-en-3-one], in or on the following raw agricultural/processed and livestock commodities: cucurbit vegetables (crop group 9) at 0.8 parts per million (ppm); fruiting vegetables (crop group 8) at 1.5 ppm; soybeans at 3 ppm; potato (crop subgroup 1C) at 1.5 ppm; poultry meat at 0.01 ppm; meat byproducts of poultry at 0.01 ppm; fat of poultry at 0.01 ppm; eggs at 0.01 ppm; milk and milk byproducts at 0.01 ppm; meat byproducts of cattle, goat, hogs, horses and sheep at 0.3 ppm; fat of cattle, goat, hogs, horses and sheep at 0.04 ppm; wet tomato peel at 3 ppm; dried tomato pomace at 40 ppm; tomato paste at 3 ppm; tomato puree at 2 ppm; dried tomatoes at 15 ppm; soy meal at 5 ppm; soy flour at 5 ppm; pollard at 4 ppm; soy aspirated grain fractions at 6 ppm; raw peeled potatoes at 3 ppm; baked potatoes with skin at 3 ppm; potato chips/fries at 2 ppm; potato granules/flakes at 5 ppm; potato process waste at 3 ppm; dried potato pulp at 3 ppm; and potato protein at 5 ppm. That document referenced a summary of the petition prepared by Syngenta Crop Protection, LLC, the registrant, which is available in the docket, <https://www.regulations.gov>. There were no comments received in response to the notice of filing.

Based on review of the data supporting the petition and EPA policy, EPA has revised some of the commodity definitions and tolerance levels from the petition. The reason for these changes are explained in Unit IV.C.

### **III. Aggregate Risk Assessment and Determination of Safety**

Section 408(b)(2)(A)(i) of FFDCFA allows EPA to establish a tolerance (the legal limit for a pesticide chemical residue in or on a food) only if EPA determines that the

tolerance is “safe.” Section 408(b)(2)(A)(ii) of FFDCA defines “safe” to mean that “there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.” This includes exposure through drinking water and in residential settings but does not include occupational exposure. Section 408(b)(2)(C) of FFDCA requires EPA to give special consideration to exposure of infants and children to the pesticide chemical residue in establishing a tolerance and to “ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue....”

Consistent with FFDCA section 408(b)(2)(D), and the factors specified in FFDCA section 408(b)(2)(D), EPA has reviewed the available scientific data and other relevant information in support of this action. EPA has sufficient data to assess the hazards of and to make a determination on aggregate exposure for spiropidion including exposure resulting from the tolerances established by this action. EPA’s assessment of exposures and risks associated with spiropidion follows.

#### *A. Toxicological Profile*

EPA has evaluated the available toxicity data and considered its validity, completeness, and reliability as well as the relationship of the results of the studies to human risk. EPA has also considered available information concerning the variability of the sensitivities of major identifiable subgroups of consumers, including infants and children. The toxicological database for spiropidion is complete and indicates that decreased body weight and mortality were the most common adverse effects observed. The dog was the most sensitive species with effects including severe clinical signs (salivation, unsteadiness on feet, ataxia, being subdued, twitching, abnormal breathing, hypersensitivity, and tremors) leading to humane euthanasia after acute, subchronic and chronic exposure at doses  $\geq 30$  mg/kg/day. No additional treatment related effects in dogs

were observed at doses that did not cause severe clinical signs. These effects occurred at doses ~4x lower and ~7x lower than the doses at which effects were observed in rats and mice, respectively. In rats, decreased body weight was observed at the highest dose tested following a 28-day exposure. Additionally, in rats, minimal to mild thyroid follicular cell hypertrophy was consistently observed across subchronic durations. In mice, premature death was observed in both sexes at the highest dose tested (448.6/465.4 mg/kg/day male/female) following subchronic exposure. At lower dose levels in mice, increased urea and blood urea nitrogen concentrations, increased alkaline phosphatase levels (females), decreased albumin levels and albumin/globulin ratio (females), and increased liver weights (males) were observed. However, these findings were not considered adverse, as there were no corroborating macroscopic or microscopic pathology findings noted in mice. Following chronic exposure in the rat and mouse, no adverse effects were observed up to the highest dose tested. Decreased body weight in males and severe convulsions in females were observed at a relatively high dose (500 mg/kg) in the acute neurotoxicity study in rats. No adverse effects were observed in rats following exposures via the dermal route up to the limit dose.

There was no evidence of increased pre- or post-natal sensitivity or susceptibility observed in the database. No adverse parental, offspring, or reproductive effects were observed in the two-generation reproductive toxicity study up to the highest dose tested. No adverse parental or developmental effects were observed in the rat and rabbit developmental toxicity studies up to the highest dose tested.

Spiropidion is classified as “Not Likely to Be Carcinogenic to Humans” based on a lack of treatment related neoplastic lesions in two species and no mutagenic concerns. Specific information on the studies received and the nature of the adverse effects caused by spiropidion as well as the no observed adverse effect level (NOAEL) and the lowest observed adverse effect level (LOAEL) from the toxicity studies can be found at

<https://www.regulations.gov> in the document entitled “Spiropidion: First Food Use; Human Health Risk Assessment for the Establishment of Permanent Tolerances without U.S. Registration for Residues in or on Soybean, Tomato, Bell and Nonbell Peppers, Muskmelon, Watermelon, Cucumber, Pumpkin, and Potato” in docket ID number EPA-HQ-OPP-2021-0356.

### *B. Toxicological Points of Departure/Levels of Concern*

Once a pesticide’s toxicological profile is determined, EPA identifies points of departure (PODs) and levels of concern (LOCs) to use in evaluating the risk posed by human exposure to the pesticide. For hazards that have a threshold below which there is no appreciable risk, the toxicological POD is used as the basis for derivation of reference values for risk assessment. PODs are developed based on a careful analysis of the doses in each toxicological study to determine the dose at which no adverse effects are observed (the NOAEL) and the lowest dose at which adverse effects of concern are identified (the LOAEL). Uncertainty/safety factors are used in conjunction with the POD to calculate a safe exposure level - generally referred to as a population-adjusted dose (PAD) or a reference dose (RfD) - and a safe margin of exposure (MOE). For non-threshold risks, the Agency assumes that any amount of exposure will lead to some degree of risk. Thus, the Agency estimates risk in terms of the probability of an occurrence of the adverse effect expected in a lifetime. For more information on the general principles EPA uses in risk characterization and a complete description of the risk assessment process, see <https://www.epa.gov/risk>.

A summary of the toxicological endpoints for spiropidion used for human risk assessment can be found in the Spiropidion Human Health Risk Assessment.

### *C. Exposure Assessment*

1. *Dietary exposure from food and feed uses.* In evaluating dietary exposure to spiropidion, EPA considered exposure under the petitioned-for tolerances. EPA assessed dietary exposures from spiropidion in food as follows:

i. *Acute exposure.* Quantitative acute dietary exposure and risk assessments are performed for a food-use pesticide, if a toxicological study has indicated the possibility of an effect of concern occurring as a result of a 1-day or single exposure. Such effects were identified for spiropidion. Acute dietary (food only) exposure and risk assessments were conducted using the Dietary Exposure Evaluation Model software with the Food Commodity Intake Database (DEEM-FCID) Version 4.02. This software uses 2005-2010 food consumption data from the U.S. Department of Agriculture's (USDA's) National Health and Nutrition Examination Survey, What We Eat in America (NHANES/WWEIA). The current assessment includes bell and nonbell pepper, cucumber, muskmelon, potato, pumpkin, soybean, tomato, watermelon, and fat and meat byproducts of cattle, goats, horses, and sheep.

EPA conducted an unrefined acute dietary (food only) exposure assessment for the proposed uses of spiropidion. EPA's default processing factors for potato dry commodities, dried tomato, tomato paste, tomato puree, and soybean flour were set to 1 as processing data for these commodities are available and no appreciable concentration of residues that would require an additional tolerance was identified. In addition, EPA's default processing factors were also used for dried bell and dried nonbell pepper. It was assumed that 100% of the crops were treated. As the request is for tolerances without U.S. registration, residues in drinking water are not expected.

Results of the acute dietary assessment indicate that the general U.S. population and all other population subgroups have exposure and risk estimates below EPA's level of concern (LOC). The acute dietary exposure estimate is 3.2% of the aPAD for the

general U.S. population, and 7.3% of the aPAD for the highest exposed population subgroup, children 1-2 years old.

ii. *Chronic exposure.* In conducting the chronic dietary (food only) exposure assessment, EPA used DEEM-FCID Version 4.02 with 2005-2010 food consumption data from the USDA's NHANES/WWEIA. EPA's default processing factors for potato dry commodities, dried tomato, tomato paste, tomato puree, and soybean flour were set to 1 as processing data for these commodities are available and no concentration of residues that would require an additional tolerance was required. In addition, EPA's default processing factors were also used for dried bell and dried nonbell pepper. It was assumed that 100% of the crops were treated. As the request is for tolerances without U.S. registration, residues in drinking water are not expected.

EPA conducted an unrefined chronic dietary (food only) exposure assessment for the proposed uses of spiropidion. Results of the chronic dietary assessment indicate that the general U.S. population and all other population subgroups have exposure and risk estimates below EPA's LOC. The chronic dietary exposure estimate is 2.3% of the cPAD for the general U.S. population, and 6.7% of the cPAD for the highest exposed population subgroup, children 1-2 years old.

iii. *Cancer.* EPA determines whether quantitative cancer exposure and risk assessments are appropriate for a food-use pesticide based on the weight of the evidence from cancer studies and other relevant data. Cancer risk is quantified using a linear or nonlinear approach. If sufficient information on the carcinogenic mode of action is available, a threshold or nonlinear approach is used and a cancer RfD is calculated based on an earlier noncancer key event. If carcinogenic mode of action data are not available, or if the mode of action data determines a mutagenic mode of action, a default linear cancer slope factor approach is utilized. Based on the data summarized in Unit III.A.,

EPA has concluded that spiropidion does not pose a cancer risk to humans. Therefore, a dietary exposure assessment for the purpose of assessing cancer risk was unnecessary.

iv. *Anticipated residue and percent crop treated (PCT) information.* EPA did not use anticipated residue and/or PCT information in the dietary assessment for spiropidion. Tolerance level residues and/or 100 PCT were assumed for all food commodities.

2. *Dietary exposure from drinking water.* Spiropidion is not registered for use in the United States; therefore, EPA assumes that there is no exposure through groundwater or surface water sources of drinking water. Because residues are not expected in drinking water, dietary risk estimates include exposures from food only.

3. *From non-dietary exposure.* The term “residential exposure” is used in this document to refer to non-occupational, non-dietary exposure (e.g., for lawn and garden pest control, indoor pest control, termiticides, and fleas and tick control on pets). Spiropidion is not registered for any specific use patterns that would result in residential exposure.

4. *Cumulative effects from substances with a common mechanism of toxicity.* Section 408(b)(2)(D)(v) of FFDCA requires that, when considering whether to establish, modify, or revoke a tolerance, the Agency consider “available information” concerning the cumulative effects of a particular pesticide’s residues and “other substances that have a common mechanism of toxicity.”

EPA has not found spiropidion to share a common mechanism of toxicity with any other substances, and spiropidion does not appear to produce a toxic metabolite produced by other substances. For the purposes of this tolerance action, EPA has assumed that spiropidion does not have a common mechanism of toxicity with other substances. For information regarding EPA’s efforts to determine which chemicals have a common mechanism of toxicity and to evaluate the cumulative effects of such chemicals, see EPA’s website at <https://www.epa.gov/pesticides/cumulative>.

#### *D. Safety Factor for Infants and Children*

1. *In general.* Section 408(b)(2)(C) of FFDCFA provides that EPA shall apply an additional ten-fold (10x) margin of safety for infants and children in the case of threshold effects to account for prenatal and postnatal toxicity and the completeness of the database on toxicity and exposure unless EPA determines, based on reliable data, that a different margin of safety will be safe for infants and children. This additional margin of safety is commonly referred to as the Food Quality Protection Act (FQPA) Safety Factor (SF). In accordance with Section 408(b)(2)(C) of the Federal Food, Drug, and Cosmetic Act (FFDCA), EPA either retains the default value of 10x margin of safety or uses a different additional safety factor when reliable data available to EPA support the choice of a different factor.

2. *Prenatal and postnatal sensitivity.* The toxicology database is complete and is adequate for the purpose of assessing prenatal and postnatal susceptibility based on the following considerations: 1) the toxicity database is complete and includes adequate studies to assess potential susceptibility in the young; 2) no effects were identified in the prenatal developmental studies or in the two-generation reproduction toxicity study up to the highest dose tested; and 3) the endpoints chosen for risk assessment are protective of any potential susceptibility that may occur at higher doses.

3. *Conclusion.* EPA has determined that reliable data show the safety of infants and children would be adequately protected if the FQPA SF of 10x were reduced to 1x.

That decision is based on the following findings:

i. The toxicology database is considered complete and is adequate for the purpose of assessing prenatal and postnatal susceptibility. Acceptable guideline studies for developmental, reproductive toxicity, and neurotoxicity are available for FQPA SF assessment.

ii. There is evidence of potential neurotoxicity in the acute neurotoxicity study (ACN) (severe convulsions in females) and in the subchronic and chronic dog studies (clinical signs indicative of potential neurotoxicity); however, concern is low because (1) the effects observed in the ACN were observed at a relatively high dose (500 mg/kg); (2) clear NOAELs were identified for the neurotoxic effects; and (3) the points of departure chosen for risk assessment are protective of any potential neurotoxicity observed in the database.

iii. There was no evidence of increased quantitative or qualitative pre-natal susceptibility in the rabbit or rat developmental toxicity studies or postnatal susceptibility in the two-generation reproduction toxicity study up to the highest doses tested. Even though these studies did not test up to the limit dose, there is little concern about the potential for toxicity and/or susceptibility at higher doses than those tested since (1) the current POD (15 mg/kg/day) is protective of any potential developmental and/or reproductive effects that may occur above the highest tested doses used in these studies (>30.6/24.1 mg/kg/day [M/F]) and (2) the dog is the more sensitive species and additional developmental and reproductive studies in the rat and rabbit are not expected to have a lower POD than currently used.

iv. There are no residual uncertainties identified in the exposure databases. An unrefined dietary exposure assessment was completed, and tolerance level residues and 100 PCT were assumed; therefore, dietary exposures will not underestimate the exposure and risks posed by spiropidion.

#### *E. Aggregate Risks and Determination of Safety*

EPA determines whether acute and chronic dietary pesticide exposures are safe by comparing aggregate exposure estimates to the aPAD and cPAD. For linear cancer risks, EPA calculates the lifetime probability of acquiring cancer given the estimated aggregate exposure. Short-, intermediate-, and chronic-term risks are evaluated by comparing the

estimated aggregate food, water, and residential exposure to the appropriate PODs to ensure that an adequate MOE exists.

1. *Acute risk.* Imported commodities will be the only source of exposure for spiropidion in the U.S.; therefore, the aggregate assessment was limited to food exposure (acute and chronic). As a result, the aggregate assessments are equivalent to the dietary assessments and are not of concern. Based on the explanation in Unit III.C.3., acute residential exposure to residues of spiropidion is not expected.

2. *Chronic risk.* Imported commodities will be the only source of exposure for spiropidion in the U.S.; therefore, the aggregate assessment was limited to food exposure (acute and chronic). As a result, the aggregate assessments are equivalent to the dietary assessments and are not of concern. Based on the explanation in Unit III.C.3., chronic residential exposure to residues of spiropidion is not expected.

3. *Short-term risk.* Short-term aggregate exposure takes into account short-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no short-term exposure scenario has been identified for spiropidion, no short-term aggregate exposure is expected.

4. *Intermediate-term risk.* Intermediate-term aggregate exposure takes into account intermediate-term residential exposure plus chronic exposure to food and water (considered to be a background exposure level). Because no intermediate-term exposure scenario has been identified for spiropidion, no intermediate-term aggregate exposure is expected.

5. *Aggregate cancer risk for U.S. population.* Based on the lack of evidence of carcinogenicity in two adequate rodent carcinogenicity studies, spiropidion is not expected to pose a cancer risk to humans.

6. *Determination of safety.* Based on these risk assessments, EPA concludes that there is a reasonable certainty that no harm will result to the general U.S. population, or to infants and children from aggregate exposure to spiropidion residues.

#### **IV. Other Considerations**

##### *A. Analytical Enforcement Methodology*

Syngenta has submitted an acceptable method description and method validation data and an independent laboratory validation (ILV) for a “Quick, Easy, Cheap, Effective, Rugged, and Safe” method (QuEChERS) liquid chromatography done with tandem mass spectroscopy (LC/MS/MS), Method No. BPL19-0035, for the determination of residues of spiropidion and metabolite SYN547305 in crop commodities for purposes of regulatory enforcement. In addition, Syngenta has submitted an acceptable method description and method validation data and an ILV for LC/MS/MS Method No. PG26LL for the determination of residues of metabolites SYN547305 (free and conjugated) in livestock commodities for purposes of regulatory enforcement.

These methods may be requested from: Analytical Chemistry Branch, Environmental Science Center, 701 Mapes Road, Suite 5350, Ft. Meade, MD 20755-5350; telephone number: (410) 305-2905; email address: *residuemethods@epa.gov*.

##### *B. International Residue Limits*

In making its tolerance decisions, EPA seeks to harmonize U.S. tolerances with international standards whenever possible, consistent with U.S. food safety standards and agricultural practices. EPA considers the international maximum residue limits (MRLs) established by the Codex Alimentarius Commission (Codex), as required by FFDC section 408(b)(4). The Codex Alimentarius is a joint United Nations Food and Agriculture Organization/World Health Organization food standards program, and it is recognized as an international food safety standards-setting organization in trade agreements to which the United States is a party. EPA may establish a tolerance that is

different from a Codex MRL; however, FFDCA section 408(b)(4) requires that EPA explain the reasons for departing from the Codex level.

The Joint Meeting on Pesticide Residues (JMPR) proposed Codex MRLs for residues of spiropidion in or on soybean; melon, watermelon, cucumber, tomato, potato, pumpkin, bell and nonbell pepper; meat byproduct of cattle, goat, hogs, horses, and sheep; fat of cattle, goat, hogs, horses, and sheep. The JMPR recommendations will be considered by the Codex Committee on Pesticide Residues (CCPR) and potentially adopted by the Codex Alimentarius Commission this year. The tolerance level for residues in pumpkin and tomato have been harmonized to the proposed Codex MRLs. The tolerance level for residues in bell and nonbell pepper have not been harmonized with the proposed Codex MRLs because the MRL is lower than the tolerance for pepper and harmonizing could result in a situation where compliance with label directions results in residues in excess of the tolerance.

### *C. Revisions to Petitioned-For Tolerances*

EPA is establishing tolerances for most of the commodities requested by the petitioner; however, a number of the tolerances being established as part of this action differ from what was initially requested in the tolerance petition. All of the revisions and/or changes to the petitioned-for tolerances and the reasoning behind those changes were presented to the petitioner and subsequently accepted. The reasoning for those revisions are explained in full detail below.

EPA revised the commodity definitions for the requested tolerances for soybeans; cucurbit vegetables (crop group 9); fruiting vegetables (crop group 8); potato (crop subgroup 1C); fat of cattle, goat, horse and sheep; and meat byproduct of cattle, goat, horse and sheep to be consistent with EPA's commodity vocabulary. Several of the requested tolerances are being established at levels that differ from what was requested based on available residue data and the use of the Organization for Economic Co-

operation and Development (OECD) MRL calculator and/or for harmonization purposes. EPA has also determined that tolerances for residues in the processed commodities of potato and tomato are not required because the tolerances for the raw commodities are sufficient to cover the processed commodities. In addition, based upon estimated dietary burden and the results of the metabolism study, hog and poultry tolerances are not needed. Further, a tolerance for milk is not being established based upon results in the ruminant feeding study in that milk does not contain residues of spiropidion.

EPA has determined that tolerances for residues in the processed commodities of soybean and pollard are not required. Soybean and pollard are considered to be minor livestock feed items, and EPA does not set tolerances for, nor does it require residue data on minor livestock feed items. The tolerance for soybean, seed is sufficient to cover these processed commodities; therefore, a tolerance for soybean and pollard are not needed. Based upon a soybean processing study, EPA has also determined that a tolerance for soybean aspirated grain fractions is not required because it is covered by the tolerance set on soybean, seed.

Although the petitioner originally requested tolerances for crop group 8, crop group 9 and crop subgroup 1C, EPA is establishing tolerances only for the representative commodities for which residue data were submitted.

## **V. Conclusion**

Therefore, tolerances are established for residues of the insecticide spiropidion and its metabolites and degradates in or on cucumber at 0.8 ppm; muskmelon at 0.9 ppm; pepper, bell at 1.5 ppm; pepper, nonbell at 1.5 ppm; potato at 1.5 ppm; pumpkin at 0.9 ppm; soybean, seed at 3 ppm; tomato at 0.8 ppm; watermelon at 0.9 ppm; cattle, fat at 0.03 ppm; cattle, meat byproducts at 0.3 ppm; goat, fat at 0.03 ppm; goat, meat byproducts at 0.3 ppm; horse, fat at 0.03ppm; horse, meat byproducts at 0.3 ppm; sheep, fat at 0.03 ppm; sheep, meat byproducts at 0.3 ppm. Compliance with tolerances for the

plant commodities will be determined by measuring only the sum of spiropidion [3-(4-chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-2-oxo-1,8-diazaspiro[4.5]dec-3-en-4-yl ethyl carbonate] and its metabolite SYN547305 [3-(4-chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-1,8-diazaspiro[4.5]decane-2,4-dione; and 2-(4-chloro-2,6-dimethyl-phenyl)-1-hydroxy-8-methoxy-4-methyl-4,8-diazaspiro[4.5]dec-1-en-3-one], calculated as the stoichiometric equivalent of spiropidion, in or on the plant commodities.

Compliance with the tolerances for the livestock commodities will be determined by measuring only SYN547305 [3-(4-chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-1,8-diazaspiro[4.5]decane-2,4-dione; and 2-(4-chloro-2,6-dimethyl-phenyl)-1-hydroxy-8-methoxy-4-methyl-4,8-diazaspiro[4.5]dec-1-en-3-one], calculated as the stoichiometric equivalent of spiropidion, in or on the livestock commodities.

## **VI. Statutory and Executive Order Reviews**

This action establishes tolerances under FFDCFA section 408(d) in response to a petition submitted to the Agency. The Office of Management and Budget (OMB) has exempted these types of actions from review under Executive Order 12866, entitled “Regulatory Planning and Review” (58 FR 51735, October 4, 1993). Because this action has been exempted from review under Executive Order 12866, this action is not subject to Executive Order 13211, entitled “Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use” (66 FR 28355, May 22, 2001) or Executive Order 13045, entitled “Protection of Children from Environmental Health Risks and Safety Risks” (62 FR 19885, April 23, 1997). This action does not contain any information collections subject to OMB approval under the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*), nor does it require any special considerations under Executive Order 12898, entitled “Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations” (59 FR 7629, February 16, 1994).

Since tolerances and exemptions that are established on the basis of a petition under FFDCA section 408(d), such as the tolerance in this final rule, do not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*), do not apply.

This action directly regulates growers, food processors, food handlers, and food retailers, not States or Tribes, nor does this action alter the relationships or distribution of power and responsibilities established by Congress in the preemption provisions of FFDCA section 408(n)(4). As such, the Agency has determined that this action will not have a substantial direct effect on States or Tribal Governments, on the relationship between the National Government and the States or Tribal Governments, or on the distribution of power and responsibilities among the various levels of government or between the Federal Government and Indian Tribes. Thus, the Agency has determined that Executive Order 13132, entitled “Federalism” (64 FR 43255, August 10, 1999), and Executive Order 13175, entitled “Consultation and Coordination with Indian Tribal Governments” (65 FR 67249, November 9, 2000), do not apply to this action. In addition, this action does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act (UMRA) (2 U.S.C. 1501 *et seq.*).

This action does not involve any technical standards that would require Agency consideration of voluntary consensus standards pursuant to section 12(d) of the National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note).

## **VII. Congressional Review Act**

Pursuant to the Congressional Review Act (5 U.S.C. 801 *et seq.*), EPA will submit a report containing this rule and other required information to the U.S. Senate, the U.S. House of Representatives, and the Comptroller General of the United States prior to

publication of the rule in the *Federal Register*. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

**List of Subjects in 40 CFR Part 180**

Environmental protection, Administrative practice and procedure, Agricultural commodities, Pesticides and pests, Reporting and recordkeeping requirements.

Dated: July 13, 2022.

**Edward Messina,**

*Director, Office of Pesticide Programs.*

Therefore, for the reasons stated in the preamble, EPA is amending 40 CFR chapter I as follows:

**PART 180—TOLERANCES AND EXEMPTIONS FOR PESTICIDE CHEMICAL RESIDUES IN FOOD**

1. The authority citation for part 180 continues to read as follows:

**Authority:** 21 U.S.C. 321(q), 346a and 371.

2. Add § 180.723 to subpart C to read as follows:

**§ 180.723 Spiropidion; tolerances for residues.**

(a) *General.* (1) Tolerances are established for residues of the insecticide spiropidion, including its metabolites and degradates, in or on the commodities in Table 1 to this paragraph (a)(1). Compliance with the tolerance levels specified in Table 1 to this paragraph (a)(1) is to be determined by measuring only the sum of spiropidion [3-(4-chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-2-oxo-1,8-diazaspiro[4.5]dec-3-en-4-yl ethyl carbonate] and its metabolite SYN547305 [3-(4-chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-1,8-diazaspiro[4.5]decane-2,4-dione; and 2-(4-chloro-2,6-dimethyl-phenyl)-1-hydroxy-8-methoxy-4-methyl-4,8-diazaspiro[4.5]dec-1-en-3-one], calculated as the stoichiometric equivalent of spiropidion, in or on the following plant commodities:

Table 1 to Paragraph (a)(1)

Commodity	Parts per million
Cucumber <sup>1</sup>	0.8
Muskmelon <sup>1</sup>	0.9
Pepper, bell <sup>1</sup>	1.5
Pepper, nonbell <sup>1</sup>	1.5
Potato <sup>1</sup>	1.5
Pumpkin <sup>1</sup>	0.9
Soybean, seed <sup>1</sup>	3
Tomato <sup>1</sup>	0.8
Watermelon <sup>1</sup>	0.9

<sup>1</sup>There are no U.S. registrations for this commodity as of [INSERT DATE OF

PUBLICATION IN THE *FEDERAL REGISTER*].

(2) Tolerances are established for residues of the insecticide spiropidion, including its metabolites and degradates, in or on the commodities in Table 2 to this paragraph (a)(2). Compliance with the tolerance levels specified in Table 2 to this paragraph (a)(2) is to be determined by measuring only SYN547305 [3-(4-chloro-2,6-dimethyl-phenyl)-8-methoxy-1-methyl-1,8-diazaspiro[4.5]decane-2,4-dione; and 2-(4-chloro-2,6-dimethyl-phenyl)-1-hydroxy-8-methoxy-4-methyl-4,8-diazaspiro[4.5]dec-1-en-3-one], calculated as the stoichiometric equivalent of spiropidion, in or on the following livestock commodities:

Table 2 to Paragraph (a)(2)

Commodity	Parts per million
Cattle, fat <sup>1</sup>	0.03
Cattle, meat byproducts <sup>1</sup>	0.3
Goat, fat <sup>1</sup>	0.03
Goat, meat byproducts <sup>1</sup>	0.3
Horse, fat <sup>1</sup>	0.03
Horse, meat byproducts <sup>1</sup>	0.3
Sheep, fat <sup>1</sup>	0.03
Sheep, meat byproducts <sup>1</sup>	0.3

<sup>1</sup>There are no U.S. registrations for this commodity as of [INSERT DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

(b) – (d) [Reserved]